

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



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JAN 26 2011

OFFICE OF PETITIONS

In re Application of: Myers, et al.
For: PROSTHETIC HEART VALVE
Serial No.: 09/772,526
U.S. Patent No.: 6,682,559
Issued: 03/29/2005

CERTIFICATE UNDER 37 CFR §1.8 I hereby certify that this Transmittal and the paper(s), as described herein are being deposited with the United States Postal Service, with sufficient postage as first class mail, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 13th day of January, 2011.

Signature

Jo L. Brecht

Printed Name

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

We are transmitting herewith the attached:

- ☒ Payment of Fees Under 37 C.F.R. § 1.28(c)(2)
☒ Return Postcard

☒ Please charge Deposit Account No. 01-2525 \$530.00 for payment of deficiencies for entity status.

☒ Please charge any additional fees or credits to Deposit Account No. 01-2525 which may have been overlooked on this Information Disclosure Statement Transmittal with regard to this filing.

USPTO
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2011 JAN 20 PM 4:23

January 12, 2011

Date

Katharine A. Jackson Huebsch, Reg. No. 47,670
Telephone: (763) 505-8423
Customer No.: 77218



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JAN 26 2011

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE OF PETITIONS

In re patent of:

Myers et al.

Patent No.: 6,682,559 (09/772,526)

Issued: March 29, 2005

For: Prosthetic Heart Valve

Confirmation No.: 9761

Art Unit: 3738

Examiner: BARRETT, Thomas C.

Atty. Docket No.: P0039821.01
(1737.3990001)

01/25/2011 DALLEN 00000023 012525 6682559

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Payment of Fees Under 37 C.F.R. § 1.28(c)(2)

Commissioner for Patents

PO Box 1450

Alexandria, VA 22313-1450

Sir:

Small entity status was established in the above-captioned application in good faith, and small entity fees were paid in good faith. However, it has recently been discovered that small entity status may have been maintained in error but in good faith, and that small entity fees therefore may have been paid in error.

The potential deficiency owed is calculated as follows:

	<u>Type of Fee</u>	<u>Small Entity Fee Paid</u>	<u>Date of Small Entity Fee Payment</u>	<u>Large Entity Fee (current schedule)</u>	<u>Deficiency Owed</u>
1.	Maintenance Fee Due at 3.5 years	\$450.00	7/27/2007	\$980.00	\$530.00
Total Owed:			Adjustment date: 02/17/2011 CKHLOK 01/25/2011 DALLEN 00000023 012525 6682559 01 FC:1599 530.00 CR \$530.00		

Payment of these fees is to be treated under 37 C.F.R. § 1.27(g)(2) as a notification of loss of entitlement to small entity status. 37 C.F.R. § 1.28(d).

Applicants properly established small entity status when the above-captioned application was filed and properly paid small entity fees up to the point in time small

entity status may have been erroneously maintained. A brief summary of the circumstances surrounding the discovery of the possibly erroneous maintenance of small entity status is provided below.

3F Therapeutics, Inc., the assignee of the above-captioned application, entered into a license agreement with Edwards Lifesciences PVT, Inc. ("Edwards") on June 2, 2005. This license agreement may have provided Edwards with a license to the above-captioned application. A redacted copy of the license agreement is attached as Exhibit A.

The current owner of the above-captioned application acquired ownership of the above-captioned application and many other patents and patent applications through a recent transaction which closed on or about August 12, 2010. During a recent review of the acquired patent and patent application assets, the current owner discovered the payments of small entity fees. Because the better practice would have been to pay large entity fees, the current owner is hereby submitting the possibly deficient fees.


Applicants respectfully request that the United States Patent and Trademark Office excuse this possible error and correct the entity status to be that of a large entity. Early notice to this effect is respectfully requested.

The Commissioner is authorized to charge the total amount owed of \$530.00 to Deposit Account No. 01-2525. The Commissioner is authorized to charge any deficiencies or credit any overpayments to our Deposit Account No. 01-2525.

The USPTO is invited to telephone the undersigned attorney at (763) 505-8426 to discuss any outstanding issues in this case.

Respectfully Submitted,

Date: Jan 10, 2011



Jeffrey J. Hohenshell, Reg. No. 34,109
Senior Patent Counsel
710 Medtronic Parkway
Minneapolis, MN 55432
Tel. (763) 505-8426
Fax (763) 505-8436
Customer No. 27581

NON-EXCLUSIVE LICENSE AGREEMENT

This LICENSE AGREEMENT ("Agreement"), dated as of June 2, 2005 (the "Effective Date"), is by and between 3F Therapeutics, Inc., a Delaware corporation ("3F"), on the one hand, and Edwards Lifesciences PVT, Inc., a Delaware corporation ("Edwards PVT"), on the other hand. Each of 3F and Edwards PVT may be referred to herein individually as a "Party" or collectively as the "Parties."

RECITALS

WHEREAS 3F is the owner of certain patents, patent applications, and know-how relating to heart valves and catheter-delivered heart valves;

WHEREAS Edwards desires to obtain a non-exclusive license to such patents, patent applications, and know-how; and

WHEREAS 3F is willing to grant such license under the following terms and conditions.

AGREEMENT

NOW, THEREFORE, in consideration of the covenants and agreements set forth herein, which constitutes good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. **Definitions.** The following definitions shall apply to the following terms:
 - 1.1 "3F" shall have the meaning set forth in the preamble.
 - 1.2 "Affiliate" shall mean, with respect to any specified Person, a Person that directly, or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control with, the Person specified.
 - 1.3 "Agreement" shall have the meaning set forth in the preamble.
 - 1.4 "Edwards PVT" shall have the meaning set forth in the preamble.
 - 1.5 "Edwards" shall mean Edwards PVT and its Affiliates.
 - 1.6 "Effective Date" shall have the meaning set forth in the preamble.
 - 1.7 "Excluded 3F IP" shall mean the patents and patent applications listed on Exhibit A hereto.
 - 1.8 "Fields of Use" shall mean the Surgical Field of Use and the Percutaneous Field of Use.
- 1.9 "PVT Product" shall mean the the Cribier-Edwards percutaneous heart valve, existing as of the Effective Date, including (i) any modifications or alterations to such valve that are made prior to the first approval by the United States Food and Drug Administration ("FDA") of a premarket approval ("PMA") application submitted on such valve in the Percutaneous Field of Use, (ii) any modifications or alterations that are made to such valve to adapt it for use in the Surgical Field of Use prior to the first approval by the FDA of a PMA application submitted on such valve in the Surgical Field of Use, and (iii) any modifications or alterations that are made to the FDA approved valves described in (i) and (ii) that do not require submission of a new PMA application.

1.10 **"Laser Patents"** shall mean the patents and patent applications listed on Exhibit B hereto, and any continuations, divisionals, reexaminations, reissues, extensions and foreign counterparts thereof.

1.11 **"Licensed Patents"** shall mean the Laser Patents and the patents and patent applications owned or licensed by 3F as of the Effective Date that relate to the Fields of Use, and any continuations, divisionals, reexaminations, reissues, extensions and foreign counterparts thereof; provided, however, that the Licensed Patents shall not include the Excluded 3F IP.

1.12 **"Licensed Product"** shall mean a product in the Fields of Use utilizing the Tissue Valve Know-How or covered by any Valid Claim of the Licensed Patents.

1.13 **"Litigation"** shall have the meaning set forth in Section 4.2.

1.14 **"Party"** shall have the meaning set forth in the preamble.

1.15 **"Parties"** shall have the meaning set forth in the preamble.

1.16 **"Percutaneous Field of Use"** shall mean the percutaneous insertion of a stented, tissue heart valve through any vessel using a catheter delivery system.

1.17 **"Person"** shall mean any individual, partnership, firm, corporation, association, trust, unincorporated organization or other entity, as well as any syndicate or group that would be deemed to be a person under Section 13(d)(3) of the Exchange Act.

1.18 **"Supply and Training Agreement"** shall mean the Supply and Training Agreement, dated June 2, 2005, by and between the Parties hereto.

1.19 **"Surgical Field of Use"** shall mean the surgical insertion through the chest cavity of a stented, tissue heart valve using a catheter delivery system of no greater than 50 centimeters in usable length (i.e., the length that can be inserted into the human body); provided, however, that such Surgical Field of Use does not include the delivery of a stented, tissue heart valve to the heart by way of any vessel other than solely through the thoracic aorta.

1.20 **"Third Party"** shall mean any Person other than 3F, Edwards, or an Affiliate of either.

1.21 "Tissue Valve Know-How" shall mean (i) any information owned or licensed by 3F or its Affiliates existing as of the termination of the Supply and Training Agreement which relate to the Fields of Use and which is listed on Exhibit C; and (ii) any information related to valve leaflets, valve subassemblies, and finished products from valve leaflets and valve subassemblies, and the processing and manufacture of valve leaflets, valve subassemblies, and finished products from valve leaflets and valve subassemblies which is used by 3F or needed by Edwards to process and manufacture valve leaflets, valve subassemblies, and finished products from valve leaflets and valve subassemblies that were being made by 3F for Edwards under the Supply and Training Agreement and which is in the possession of 3F or its Affiliates at any time prior to the termination of the Supply and Training Agreement.

1.22 "Valid Claim" shall mean a claim of an issued and unexpired patent included in the Licensed Patents which has not been revoked or held unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and which has not been disclaimed, denied, or admitted to be invalid or otherwise unenforceable through reissue, reexamination, disclaimer, or otherwise.

2. License Grants.

2.1 3F hereby grants to Edwards a worldwide, non-transferable (except as set forth in Section 10.2.1 below), royalty free, non-exclusive license under the Licensed Patents, except for the Laser Patents, without the right to sublicense, to manufacture, have manufactured, use, import, offer for sale, and sell Licensed Products only in the Surgical Field of Use and/or the Percutaneous Field of Use.

2.2 3F hereby grants to Edwards a worldwide, non-transferable (except as set forth in Section 10.2.1 below), royalty free, non-exclusive license under the Laser Patents, without the right to sublicense, to manufacture, have manufactured, use, import, offer for sale, and sell PVT Products only in the Surgical Field of Use and/or the Percutaneous Field of Use.

2.3 3F hereby grants to Edwards a worldwide, non-transferable (except as set forth in Section 10.2.1 below), royalty free, non-exclusive license to the Tissue Valve Know-How, without the right to sublicense, to manufacture, have manufactured, use, import, offer for sale, and sell Licensed Products only in the Fields of Use.

2.4 Edwards agrees and acknowledges that the limited scope of the Fields of Use set forth in this Agreement are a material and essential part of this Agreement. As such, the licenses set forth in this Section 2 include a covenant by Edwards to refrain from taking any actions that would permit, encourage, promote, market, fund, sponsor, or facilitate, directly or indirectly, any off label use or any other use of any Licensed Product outside the Fields of Use, and to use its best efforts to prevent any such off label use or any other use outside the Fields of Use. Any breach by Edwards of this covenant shall be deemed a material breach of this Agreement.

2.5 No implied patent or other intellectual property rights or licenses are granted by 3F hereunder or in connection herewith other than those licenses expressly granted in this Agreement.

2.6 Nothing in this Agreement shall limit or preclude Edwards use of, in any manner or in any field, the Tissue Valve Know-How, that (i) is or becomes publicly known (through no wrongful act, omission, or breach of this Agreement by Edwards); (ii) is already known to Edwards or its Affiliates at the time that such Tissue Valve Know-How is transferred to Edwards; (iii) is independently developed by Edwards or its Affiliates without the benefit of the Tissue Valve Know-How; or (iv) is rightfully received or obtained by Edwards or its Affiliates independent of the transfer of the Tissue Valve Know-How by 3F.

3. **Product Labeling.**

3.1 Upon written notice from 3F of a specific Licensed Patent that applies to a specific Licensed Product, each Licensed Product sold by Edwards shall be marked in compliance with 35 U.S.C. § 287, or the relevant corresponding statute under the law of the country in which such Licensed Product is sold.

3.2 Each Licensed Product manufactured by or for Edwards shall be labeled for use only in the Fields of Use.

4. **Infringement and Enforcement.**

4.1 If at any time during the term of this Agreement, Edwards learns or believes that any Third Party is infringing any of the Licensed Patents or using Tissue Valve Know-How without a license in the Fields of Use, Edwards shall notify 3F in writing of the existence of such alleged infringement or unlicensed use.

4.2 3F may, but has no obligation to, take any and all actions to enforce the Licensed Patents (including without limitation instituting litigation) against any infringement in the Fields of Use or to prevent any unlicensed use of the Tissue Valve Know-How ("Litigation"). 3F shall bear all the expenses and costs with respect to any such Litigation and 3F shall be entitled to all damages recovered in such Litigation.

4.3 At 3F's request, Edwards agrees to cooperate in any such Litigation, including but not limited to participating in such Litigation as a named party. 3F agrees to pay Edward's reasonable costs and expenses in connection with such Litigation. In the event that Edwards desires to retain separate counsel in connection with such Litigation, however, Edwards shall bear its own costs and expenses concerning the Litigation, including without limitation the costs and expenses of such separate counsel. Notwithstanding Edward's participation in such Litigation, 3F shall retain the full right to control such Litigation, including without limitation any settlement of such Litigation. 3F shall have the right, in its sole and absolute discretion, to settle any Litigation on such terms and conditions that 3F deems to be appropriate.

5. **Representations and Warranties.**

5.1 3F hereby represents and warrants to Edwards that

(i) it has all of the requisite power and authority to enter into this Agreement and to perform its obligations hereunder and that this Agreement has been duly and validly authorized, executed, and delivered by 3F;

(ii) it is the owner of, or has the exclusive license to, the Tissue Valve Know-How, such Tissue Valve Know-How, to the best of 3F's knowledge, does not infringe or misappropriate the intellectual property of any Third Party, and that 3F has the entire right to enter these licenses; and

(iii) it is the owner of, or has the exclusive license to, the Licensed Patents and that it has the entire right to enter into these licenses.

5.2 EXCEPT AS EXPRESSLY SET FORTH IN SECTION 5.1 AND TO THE EXTENT THAT 3F PROVIDES NOTICE IN ACCORDANCE WITH SECTION 3.1, 3F DOES NOT MAKE, AND THERE ARE NO, WARRANTIES, REPRESENTATIONS, OR CONDITIONS, EXPRESS OR IMPLIED, STATUTORY OR OTHERWISE RELATING TO THE LICENSED PATENTS OR TISSUE VALVE KNOW-HOW, INCLUDING WITHOUT LIMITATION ANY REPRESENTATIONS OR WARRANTIES OF VALIDITY, ENFORCEABILITY, NON-INFRINGEMENT, OR FITNESS FOR ANY PARTICULAR PURPOSE.

5.3 Edwards hereby represents and warrants to 3F that it has all of the requisite power and authority to enter into this Agreement and that this Agreement has been duly and validly authorized, executed, and delivered by Edwards.

6. Term and Termination.

6.1 The term of this Agreement shall commence on the Effective Date and, subject to earlier termination as provided herein, shall continue until the later of: (i) the date of expiration of the last to expire of any Licensed Patent covering a Licensed Product; or (ii) the date on which Edwards no longer intends to utilize the Tissue Valve Know-How. Edwards shall promptly notify 3F at such time that Edwards no longer intends to utilize the Tissue Valve Know-How.

6.2 Either Party may terminate this Agreement for a material breach by the other Party that remains uncured for ninety (90) days following notice to the breaching Party.

6.3 This Agreement, including all licenses herein, shall automatically and immediately terminate, without any further action or notice by 3F, in the event that Edwards is or becomes insolvent. For purposes of this Agreement, Edwards shall be deemed "insolvent" if it is unable to pay its debts and obligations as and when they come due.

7. Notices.

Any notice which is required or permitted to be given to a Party pursuant to this Agreement shall be deemed to have been given only if such notice is reduced to writing and (i) delivered personally, (ii) sent by reputable overnight courier service for next business day delivery to the person in question at the address given below, or (iii) sent by facsimile machine (with proof transmission capability) to the fax number set forth below, with a hard copy to be sent by first class mail to the person at the address given below:

If to 3F:

3F Therapeutics, Inc.
20412 James Bay Circle
Lake Forest, CA 92630
Facsimile No.: (949) 380-9399
Attn: Walter A. Cuevas

with a copy to (which copy shall not
constitute notice):

Reed Smith, LLP
1901 Avenue of the Stars, Suite 700
Los Angeles, CA 90067
Facsimile No.: (310) 734-5299
Attn: Michael Sanders

If to Edwards:

Edwards Lifesciences PVT, Inc.
One Edwards Way
Irvine, CA 92614
Facsimile No.: (949) 250-6868
Attn: General Counsel

with a copy to (which copy shall not
constitute notice):

Gibson, Dunn & Crutcher LLP
Jamboree Center
4 Park Plaza
Irvine, CA 92614
Facsimile No.: (949) 475-4673
Attn: John M. Williams

or to such other address or facsimile number as either Party shall have specified by notice in writing to the other Party.

If delivered personally or by facsimile during normal business hours on a business day, a notice shall be deemed delivered when actually received at the address specified above. In any other case, notice shall be deemed delivered on the next business day following the date on which it was sent.

8. **Indemnification.**

8.1 Edwards shall indemnify, defend, and hold 3F harmless against any and all losses arising out of a Third Party claim to the extent such claim arises from the negligence, willful misconduct, breach of contract, or violations of law by Edwards, its employees, agents, subcontractors, or assigns in the performance of this Agreement. The losses covered by this Section 8.1 include, but are not limited to, settlements, judgments (court costs, attorneys' fees, expert fees, and other litigation expenses), fines and penalties arising out of actual or alleged (i) injury to or death of any person; (ii) loss of or damage to tangible or intangible property; (iii) patent mismarking; and (iv) breach of contract.

8.2 3F shall indemnify, defend, and hold Edwards harmless against any and all losses arising out of a Third Party claim to the extent such claim arises from the negligence, willful misconduct, breach of contract, or violations of law by 3F, its employees, agents, subcontractors, or assigns in the performance of this Agreement. The losses covered by this Section 8.2 include, but are not limited to, settlements, judgments (court costs, attorneys' fees, expert fees, and other litigation expenses), fines and penalties arising out of actual or alleged (i) loss of or damage to intangible property; (ii) patent mismarking to the extent that 3F provides notice pursuant to Section 3.1; and (iii) breach of contract.

9. **Limitation of Liability or Damages.**

9.1 EXCEPT WITH RESPECT TO EACH PARTY'S RESPECTIVE INDEMNITY OBLIGATIONS PURSUANT TO SECTION 8, IN NO EVENT SHALL EITHER PARTY, ITS AGENTS, OR EMPLOYEES BE LIABLE TO THE OTHER PARTY FOR ANY INDIRECT, SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES, OR ANY PUNITIVE DAMAGES, INCLUDING WITHOUT LIMITATION LOST PROFITS, IN CONNECTION WITH THIS AGREEMENT, THE LICENSED PATENTS, OR TISSUE VALVE KNOW-HOW, HOWEVER SO CAUSED, WHETHER ARISING IN CONTRACT (INCLUDING BREACH), TORT (INCLUDING NEGLIGENCE), OR OTHERWISE. The Parties acknowledge and agree that the exclusion of liability herein is reasonable and appropriate in the circumstances and was a material factor in determining the terms of this Agreement.

9.2 Without limiting the generality of Section 9.1 and except as 3F provides notice in accordance with Section 3.1, nothing contained in this Agreement shall be construed as:

- (i) requiring the enforcement of any patent or patent application, including any obligation by 3F to institute any suit or action for infringement of any of the Licensed Patents;
- (ii) reflecting a determination by 3F of the applicability of any of the Licensed Patents to the Fields of Use or any Licensed Product of Edwards;
- (iii) a warranty or representation by 3F as to the validity or scope of any Licensed Patents; or
- (iv) any obligation by 3F to furnish any assistance under this Agreement; provided, however, that this subsection (iv) shall not limit any of 3F's obligations pursuant to the Supply and Training Agreement.

10. **Miscellaneous.**

10.1 **Relationship of the Parties.** Nothing in this Agreement shall be construed to create a partnership, joint venture, employment or agency relationship, or any other form of legal association between 3F and Edwards. Except as expressly set forth in this Agreement, each Party shall conduct business in its own name and shall be solely responsible for the acts and conduct of its employees and agents.

10.2 **Assignability.**

10.2.1 This Agreement is not assignable or transferable by Edwards, in whole or in part, except (i) with the prior written consent of 3F; (ii) an assignment in connection with the sale of all or substantially all of Edwards' business; (iii) an assignment by Edwards to a purchaser of all or substantially all of the assets of the business relating to the Tissue Valve Know-How; or (iv) the licenses set forth in Section 2 can be separately assigned by Edwards to a purchaser of all or substantially all of the assets of the business relating to any of the Fields of Use, as applicable; provided, however, that in the event of any assignment pursuant to this

Section, such assignee shall agree to be bound and comply with all of the applicable obligations of this Agreement. By way of example, in connection with subsection (iv) of this Section, if Edwards sells all or substantially all of its business relating to the Surgical Field of Use, the licenses set forth in Sections 2.1, 2.2 and 2.3 relating to the Surgical Field of Use may be assigned to the purchaser of such business, provided such assignee agrees to be bound and comply with all of the obligations of this Agreement related to such assigned licenses, including without limitation, for example, Sections 2.4, 3, 4, 8.1, 9, and 10.

10.2.2 3F may assign or transfer this Agreement, in whole or in part; provided, however, that 3F provide written notice to Edwards and that such assignee agrees to be bound and comply with all applicable obligations of this Agreement.

10.3 **Governing Law.** This Agreement shall be governed by and construed in accordance with the internal laws of the State of California, without giving effect to the choice of law rules thereof. Each of the Parties hereto irrevocably consents to the jurisdiction of the state and federal courts located within Orange County, State of California, and irrevocably agrees that all actions or proceedings relating to this Agreement, the Licensed Patents, or the Tissue Valve Know-How shall be litigated in such courts, and each of the Parties expressly waives any objection or defenses that it may have based on lack of personal jurisdiction, improper venue, or forum *non conveniens* with respect to such courts. The Parties' consent and waiver set forth in this Section 10.3 expressly shall apply in the event that any such action is transferred by the United States District Court sitting in Orange County, on its own motion or upon filing, to any other division of the United States District Court for the Central District of California.

10.4 **Attorneys' Fees.** If any Party to this Agreement shall bring any action, suit, arbitration, mediation, counterclaim or appeal for any relief against any other Party, declaratory or otherwise, to enforce the terms hereof or to declare rights hereunder, the Prevailing Party in such action shall be entitled to recover as recoverable costs in any such action its attorneys' fees and costs (including reasonable fees and costs for in-house counsel), all expert fees and costs, all court and/or arbitration expenses, and any other costs reasonably and properly incurred, including any fees and costs incurred in bringing and prosecuting such action and/or enforcing any order, judgment, ruling, or award granted as part of such action. As used in this Section, "Prevailing Party" shall include, without limitation, a party who agrees to dismiss an action or who obtains substantially the relief sought by it.

10.5 **Counterparts.** This Agreement may be executed in two or more counterparts (including by means of facsimile), each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

10.6 **Severability.** Should any part or provision of this Agreement be rendered or declared invalid by reason of any law or by decree of a court of competent jurisdiction, the validity of any other term, clause, or provision shall not be affected provided that such invalid or unenforceable provision is and can be replaced with an enforceable clause which most closely achieves the result intended by such invalid clause.

10.7 **Survivability.** The provisions of Sections 1, 4, 5, 8, 9, and 10 shall survive any termination or expiration of this Agreement.

10.8 **Headings.** The headings used in this Agreement are for purpose of reference only and shall not affect the meaning or interpretation of any provision of this Agreement.

10.9 **Drafting.** Each Party has had the opportunity to consult with competent, independent counsel in connection with this Agreement and has participated in the drafting of this Agreement. Accordingly, this Agreement shall not be construed against either Party as the drafter.

10.10 **Waiver.** No waiver or delay by either Party of any breach of the covenants contained herein to be performed by the other Party shall be construed as a waiver of any succeeding breach of the same or any other covenants or conditions hereof.

10.11 **Entirety of Agreement.** This Agreement supersedes any prior understandings or agreements, whether written or oral, and any contemporaneous oral agreements, between the Parties hereto in regard to the subject matter hereof and, together with the Master Agreement and other Related Agreements (as defined in the Master Agreement), contain the entire agreement between the Parties in regard to the subject matter hereof. This Agreement may not be changed or modified orally, but only by an agreement, in writing, signed by all parties hereto.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed and delivered by their duly authorized representations, effective as of the Effective Date set forth above.

3F THERAPEUTICS, INC.

EDWARDS LIFESCIENCES PVT, INC.

By: /s/ Walter Cuevas

Name: Walter Cuevas

Title: President and Chief Executive Officer

By: /s/ Jay P. Wertheim

Name: Jay P. Wertheim

Title: Vice President, Associate General
Counsel and Secretary